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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,546	03/20/2001	Karl Kolter	51284	9100

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EXAMINER

SILVERMAN, ERIC E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,546

Applicant(s)

KOLTER ET AL.

Examiner

Eric E. Silverman, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-19 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-19, 21-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Election/Restrictions

Newly submitted claims 25 and 26 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The new claims are drawn to a process of making, whereas the original claims are drawn to a product made thereby. The process of making claims require that the formulation be made with steps such as melt extrusion, film coating, and press coating. The product could be made by materially different methods, such as by granulation. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25 and 26 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

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All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3 – 19, 21 – 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “facilitates said delayed release”. It is unclear what is meant by “facilitating delayed release”. Furthermore, the claim recites “said formulation”, which lacks antecedent basis (recitation of “said” indicates that there ought to be antecedent basis for “formulation” earlier in the claim). Claim 1 also recites “low or high molecular weight lipophilic additives”. Absent a limiting definition in the specification, it is not clear what molecular weights are “low” or “high” as recited, and as such the artisan would not understand the metes and bounds of the invention. Claim 1 also recites a “formulated

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mixture". Absent a limiting definition in the specification, it is not clear what constitutes a "formulated" mixture as opposed to a mixture that is not "formulated, and as such the artisan would not understand the metes and bounds of the invention. Clarification is requested.

The remaining claims are rejected at least for depending on claim 1 without clarifying these issues.

Regarding claim10, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Furthermore, it is not clear if all of the recited ingredients need be present, or if only one need be present, to satisfy the limitation of this claim. For the purposes of compact prosecution, Examiner will interpret the claim to mean that the presence of one or more of the ingredients will satisfy the limitations of the claim.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3 – 19, and 21 – 24 **remain** rejected under 35 U.S.C. 102(b) as being anticipated by Kolter et al., DE 197 09 663 A1, wherein US 6,066,334 is relied upon as an English translation, for reasons of record and those discussed below.

Response to Arguments

Applicants' argument have been fully considered, but are not persuasive.

At the outset, for the purposes of clarification it is noted that, contrary to Applicants' remarks on page 7 of Response filed 5/22/2006, the rejection of record is based on the German document DE 197 09 663 A1, dated March 10, 1997, and the US patent is relied on merely as a translation of the German document. This is deemed to be important, since the US patent does not qualify as prior art under 35 U.S.C. 102(b) based on its issue date of May 23, 2000, whereas the German document does qualify as art under this statute based on its earlier publication date.

Applicant argues that Kolter does not teach a "delayed release" dosage form. However, it is noted that the ingredients of Kolter's composition are identical to those of instant claims, are present in amounts commensurate therewith. A composition is defined by its ingredients and how those ingredients are disposed relative to one another. Since instant claims do not recite how the ingredients are disposed relative to one another, only the identity and amount of ingredients is relevant in this case. The terms used to describe the composition are not germane, since the properties of a composition are not separable from the composition itself. As such, since the composition of Kolter has the same ingredients in the same amounts as that recited in instant claims, Kolter anticipates instant claims. That the terms used by Applicants and Kolter to describe the nature or properties of the composition may differ is mere semantics.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3 – 19, 24 – 24 **remain** under 35 U.S.C. 103(a) as being unpatentable over Kolter et al., DE 197 09 663 A1, wherein US 6,066,334 is relied upon as an English translation, in view of US 4,837,032 to Ortega for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicant argues that Ortega does not disclose PVP mixed with PVAc. However, this limitation is clearly taught by Kolter. As discussed in the previous action, Ortega is relied on for teaching that the release rate can be altered by changing the amounts of binders, and that this is desirable to do in order to treat certain types of conditions or when using certain types of active agents. With regard to the argument that the binders of Ortega are not the same as those of Kolter, and as such the artisan would not understand that the teachings of Ortega are applicable to Kolter, Examiner notes as evidence to the contrary the teachings of Remington: The Science and Practice of Pharmacy, which teaches that although a variety of materials can be used as binders, the purpose of binders is nonetheless the same. Remington also reinforces the teachings of Kolter by noting that the properties of a tablet, such as disintegration rate, will depend on the amount of binder, (page 1617). As such, the artisan would understand that the teachings of Ortega could be applied to Kolter, and thus the artisan

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would enjoy a reasonable expectation of success at optimizing the release rate in order to use the dosage form for effective treatment of a condition of interest.

Conclusion

No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Eric E. Silverman, PhD
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